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Michael P Dilworth  
Dilworth & Barrese  
333 Earle Ovington Blvd  
Uniondale, NY 11553

EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 04/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/543,268

Applicant(s)

BOYCE ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-94 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-94 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

***Specification***

1. The disclosure is objected to because of the following informalities:
2. On page 1 of the specification, there is no continuing data indicating that the present application is a continuation of serial number 09/020,205 which is now US Patent 6,123,731.

Appropriate correction is required.

***Terminal Disclaimer***

3. The terminal disclaimer filed February 12, 2002 does not comply with 37 CFR 1.321(b) and/or (c) because:

The person who has signed the disclaimer has not stated the extent of his/her interest, or the business entity's interest, in the application/patent. See 37 CFR 1.321(b)(3).

***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-72 of U.S. Patent No.

6,123,731. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are read on by the patented claims such that they are clearly obvious thereover and have overlapping coverage.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 13, 14, 19-23, 34-45, 56-63, 74-82, and 93-94 are rejected under 35 U.S.C. 102(b) as being anticipated by Lyle (US 5,061,286) wherein demineralized bone particles have had their minerals removed such that the surfaces thereof are collagen. In addition, the particles are linked together with the binder such as cyanoacrylate; see the whole document, especially column 2, lines 63-68 and column 4, lines 12-20.

With regard to claim 6 specifically, the figures show a ring shaped cross-section around the hip implant stem.

With regard to claims 7, 22, 23, 44, and 45, the material of Lyle is a solid material so it inherently has a tensile strength even though one is not disclosed. Since the Office does not have testing facilities to determine the tensile strength thereof, the Examiner hereby asserts that the tensile strength of Lyle is within the claimed range and hereby burdens the Applicant to show otherwise.

With regard to claims 13, 14, 24, 36, 40, 58, and 76, the limitations set forth in these claims are process limitations even though the claims are drawn to a product. For

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this reason, the Examiner asserts that the claimed product is fully met by Lyle even though a different method was used to make it because bonds with the collagen and binding agent are present; see MPEP 2113 which is incorporated herein by reference thereto.

Claims 1-5, 7, 11-14, 16, 19-21, and 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Jefferies (US 4,394,370) wherein the demineralized bone particles have surface exposed collagen which is crosslinked resulting in increased mechanical strength; in other words bonds are formed between the particles via the crosslinking agent to improve mechanical strength; see the whole document, especially Example I and column 4, lines 4-14.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyle (US 5,061,286) alone. Lyle discloses the use of a binding agent in general and of a crosslinking molecule of cyanoacrylate specifically but does not disclose the use of the particular crosslinking agents as claimed. However, the Examiner posits that it would have been obvious to use another crosslinking agent in view of the broad teaching of Lyle for a binding agent absent some showing that the particular agent had some unexpected/unobvious result.

***Allowable Subject Matter***

Claims 24-33, 46-55, 64-73, and 83-92 are rejected under double patenting doctrine only. If the double patenting rejection were overcome, these claims would be objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

5. Applicant's arguments filed February 12, 2002 have been fully considered but they are not persuasive.

6. In response to the traversal of the Lyle 35 USC 102(b) rejection that Lyle does not teach binding of particles to each other, the Examiner posits that the cement of adhesive of Lyle provides the chemical linkages to bind the particles together. Furthermore, there is no claim language which precludes an intermediate chemical structure. For this reason, the claim language is fully met.

7. Applicants traverse the Jefferies 35 USC 102(b) rejection by arguing that it does not disclose reinforcing particles or fillers. However, the Examiner posits that at least collagen is the filler material. In addition, Example III discloses another filler in the form of macromolecules.

8. Finally, Applicants traverse Jefferies by stating that there is no reinforcement component therein. However, the claims only require reinforcing particles. The filler need not have a reinforcing function. Nonetheless, the filler of Jefferies (i.e. collagen or macromolecules) provide reinforcement by serving as vehicles for chemical bonding.

***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned problem is corrected.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic  
Primary Examiner  
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